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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

JOHN PELS, on behalf of himself and all others  
similarly situated,

Plaintiff,

v.

KEURIG DR. PEPPER, INC.,

Defendant.

Case No. 3:19-cv-03052-SI

**PLAINTIFF'S OPPOSITION TO  
DEFENDANT'S MOTION TO DISMISS  
AMENDED CLASS ACTION  
COMPLAINT**

**TABLE OF CONTENTS**

1		
2	INTRODUCTION .....	1
3	FACTUAL ALLEGATIONS .....	2
4	SUMMARY OF ARGUMENT .....	4
5	ARGUMENT.....	8
6	I.    Plaintiff Has Pled All Elements of a Consumer Law Violation. ....	8
7	A.    Keurig Has Acted Unlawfully. ....	8
8	B.    Plaintiff Has Alleged Injury in Fact. ....	9
9	C.    Plaintiff’s Damages and Restitution Claims Are Not Moot. ....	11
10	D.    Plaintiff Did Not Need to Allege a Specific Purchase Date. ....	11
11	E.    Plaintiff Has Adequately Pled Reliance. ....	12
12	F.    Plaintiff’s Plead Their Claims with Sufficient Specificity. ....	14
13	G.    Plaintiff Adequately Alleges Keurig’s Knowledge of Illegal Arsenic Levels. ....	15
14	H.    Plaintiff Has Standing to Seek an Injunction.....	15
15	II.    Keurig’s Preemption Argument Is Procedurally Premature and Substantively Flawed.....	17
16	III.   The Primary Jurisdiction Doctrine Is Inapplicable.....	21
17	A.    Keurig Presents No Evidence to Support Primary Jurisdiction.....	21
18	B.    Keurig Fails to Meet the High Threshold for Primary Jurisdiction.....	21
19	CONCLUSION .....	23

## Table of Authorities

### Cases

<i>Ang v. Bimbo Bakeries USA, Inc.</i> ,	
No. 13-cv-1196-WHO, 2013 U.S. Dist. LEXIS 138897, (N.D. Cal. Sept. 25, 2013).....	12
<i>Arabian v. Organic Candy Factory.</i> ,	
No. 2:17-cv-05410-ODW-PLAx, 2018 U.S. Dist. LEXIS 45833, 2018 WL 1406608 (C.D. Cal.	
Mar. 19, 2018) .....	16
<i>Astiana v. Hain Celestial Grp., Inc.</i> ,	
783 F. 3d 753, (9th Cir. 2015) .....	22
<i>Auer v. Robbins.</i> ,	
519 U.S. 452, (1997) .....	5
<i>Backus v. Gen. Mills.</i> ,	
122 F. Supp. 3d 909, (N.D. Cal. 2015).....	9
<i>Bartholomew v. Finke.</i> ,	
No. 18-cv-04590-CRB, 2019 U.S. Dist. LEXIS 11080, (N.D. Cal. Jan. 23, 2019) .....	7
<i>Boysen v. Walgreen Co.</i> ,	
No. C 11-06262 SI, 2012 U.S. Dist. LEXIS 100528 (N.D. Cal. July 19, 2012).....	6, 10
<i>Brod v. Sioux Honey Ass’n, Co-op.</i> ,	
927 F. Supp. 2d 811, (N.D. Cal. 2013), <i>aff’d</i> , 609 F. App’x 415 (9th Cir. 2015).....	9
<i>Bruton v. Gerber Products Co.</i> ,	
No. 12-cv-2412-LHK, 2014 U.S. Dist. LEXIS 5493, (N.D. Cal. Jan. 15, 2014).....	12
<i>Campen v. Frito-Lay N. Am., Inc.</i> ,	
No. 12-1586 SC, 2013 U.S. Dist. LEXIS 47126 (N.D. Cal. Apr. 1, 2013).....	14
<i>Coverdell v. Dep’t of Soc. &amp; Health Servs.</i> ,	
834 F.2d 758, (9th Cir. 1987) .....	7
<i>Hawyuan Yu v. Dr Pepper Snapple Grp., Inc.</i> ,	
No. 18-cv-06664-BLF, 2019 U.S. Dist. LEXIS 102023, (N.D. Cal. June 18, 2019).....	7

1	<i>Organic Consumers Ass'n v. General Mills, Inc.</i> ,	
2	2017 D.C. Super. LEXIS 4, (D. D.C. July 6, 2017) .....	12
3	<i>Chacanaca v. Quaker Oats Co.</i> ,	
4	752 F. Supp. 2d 1111, (N.D. Cal. 2010).....	23
5	<i>Chavez v. Blue Sky Natural Beverage Co.</i> ,	
6	340 F. App'x 359, (9th Cir. 2009).....	9, 22
7	<i>Chowning v. Kohl's Dep't Stores, Inc.</i> ,	
8	733 F. App'x 404, (9th Cir. 2018).....	11
9	<i>Cipollone v. Liggett Group, Inc.</i> ,	
10	505 U.S. 504, (1992) .....	18
11	<i>Clancy v. The Bromley Tea Co.</i> ,	
12	308 F.R.D. 564, (N. D. Cal. 2013) .....	12
13	<i>Clark v. Time Warner Cable</i> ,	
14	523 F.3d 1110, (9th Cir. 2008) .....	21
15	<i>Clark v. WorldMark.</i> ,	
16	No. 1:18-cv-01661-LJO-JLT, 2019 U.S. Dist. LEXIS 124445, (E.D. Cal. July 25, 2019) .....	14
17	<i>Clay v. Cytosport, Inc.</i> ,	
18	No. 15-CV-165 L DHB, 2015 U.S. Dist. LEXIS 110447, (S.D. Cal. Aug. 19, 2015 .....	19, 20
19	<i>Coverdell v. Dep't of Soc. &amp; Health Servs.</i> ,	
20	834 F.2d 758, (9th Cir. 1987) .....	5, 21
21	<i>Dana v. Hershey Co.</i> ,	
22	180 F. Supp. 3d 652, (N.D. Cal. 2016).....	11
23	<i>Daniel v. Ford Motor Co.</i> ,	
24	806 F.3d 1217, (9th Cir. 2015) .....	13, 14
25	<i>Durnford v. MusclePharm Corp.</i> ,	
26	907 F.3d 595, (9th Cir. 2018) .....	18
27	<i>Gonzalez v. Costco Wholesale Corp.</i> ,	
28	No. 16-CV-2590 (NGG) (JO), 2018 U.S. Dist. LEXIS 171000 (E.D.N.Y. Sep. 29, 2018).....	16

1	<i>Goodman v. HTC Am., Inc.,</i>	
2	No. C11-1793MJP, 2012 U.S. Dist. LEXIS 88496, (W.D. Wash. June 26, 2012) .....	14
3	<i>Gubula v. CVS Pharm., Inc.,</i>	
4	No. 14 C 9039, 2016 U.S. Dist. LEXIS 32759 (N.D. Ill. Mar. 15, 2016).....	18, 20
5	<i>Haddix v. Gen. Mills, Inc.,</i>	
6	No. 2:15-cv-02625-MCE-AC, 2016 U.S. Dist. LEXIS 65108, (E.D. Cal. May 17, 2016).....	11
7	<i>Hawyuan Yu v. Dr Pepper Snapple Grp., Inc.,</i>	
8	No. 18-cv-06664-BLF, 2019 U.S. Dist. LEXIS 102023, (N.D. Cal. June 18, 2019).....	15
9	<i>Hinojos v. Kohl's Corp.</i>	
10	718 F.3d 1098, (9th Cir. 2013) .....	9
11	<i>Hodsdon v. Mars, Inc.,</i>	
12	891 F.3d 857, (9th Cir. 2018) .....	13
13	<i>In re 5-Hour Energy Mktg. &amp; Sales Practices Litig.,</i>	
14	No. MDL 13-2438 PSG (PLAx) 2014 U.S. Dist. LEXIS 149732 (C.D. Cal. Sep. 14, 2014).....	22
15	<i>In re Morning Song Bird Food Litig.,</i>	
16	No. 12-cv-1592 JAH (RBB), 2013 U.S. Dist. LEXIS 149153, (S.D. Cal. Sep. 30, 2013) .....	9
17	<i>In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, &amp; Prods. Liab. Litig.,</i>	
18	754 F. Supp. 2d 1145, (C.D. Cal. 2010) .....	22
19	<i>In re: Whole Foods Market Inc.,</i>	
20	163 F. Supp. 3d 385 (W.D. Tex. 2016) .....	18, 19
21	<i>Jones v. ConAgra Foods, Inc.,</i>	
22	912 F. Supp. 2d 889, (N.D. Cal. 2012).....	23
23	<i>Jordan v. Paul Fin., LLC.,</i>	
24	745 F. Supp. 2d 1084, (N.D. Cal. 2010).....	14
25	<i>Kellman v. Whole Foods Mkt., Inc.,</i>	
26	313 F. Supp. 3d 1031 (N.D. Cal. 2018).....	13
27	<i>Kent v. DaimlerChrysler Corp.,</i>	
28	200 F. Supp. 2d 1208, (N.D. Cal. 2002) .....	22

1	<i>Kurtz v. Kimberly-Clark Corp.</i> ,	
2	321 F.R.D. 482, (E.D.N.Y. 2017).....	16
3	<i>Lassen v. Nissan N. Am., Inc.</i> ,	
4	211 F. Supp. 3d 1267, (C.D. Cal. 2016) .....	10
5	<i>Lewis v. Rodan &amp; Fields, LLC.</i> ,	
6	No. 18-cv-02248-PJH, 2019 U.S. Dist. LEXIS 32470,(N.D. Cal. Feb. 28, 2019).....	13
7	<i>Lusnak v. Bank of Am. N.A.</i> ,	
8	883 F.2d 1185, (9th Cir. 2018) .....	18
9	<i>Maya v. Centex Corp.</i> ,	
10	658 F.3d 1060, (9th Cir. 2011) .....	6
11	<i>Mayfield v. United States.</i> ,	
12	599 F.3d 964, (9th Cir. 2010) .....	17
13	<i>Mee v. I A Nutrition, Inc.</i> ,	
14	No. C-14-5006 MMC, 2015 U.S. Dist. LEXIS 63038, (N.D. Cal. May 13, 2015).....	18
15	<i>Nader v. Allegheny Airlines, Inc.</i> ,	
16	26 U.S. 290, (1976) .....	22
17	<i>Nguyen v. Biter.</i> ,	
18	No. 1:11-cv-00809-AWI-SKO (PC), 2015 U.S. Dist. LEXIS 119406 (E.D. Cal. Sep. 7, 2015)...	10
19	<i>Odom v. Microsoft Corp.</i> ,	
20	486 F.3d 541, (9th Cir. 2007) .....	15
21	<i>Philips v. Ford Motor Co.</i> ,	
22	No. 14-cv-02989-LHK, 2016 U.S. Dist. LEXIS 22020, (N.D. Cal. Feb. 22, 2016) .....	22
23	<i>Pom Wonderful Ltd. Liab. Co. v. Ocean Spray Cranberries Inc.</i> ,	
24	642 F. Supp. 2d 1112, (C.D. Cal. 2009) .....	7
25	<i>Reid v. Johnson &amp; Johnson.</i> ,	
26	780 F.3d 952, (9th Cir. 2015) .....	6
27	<i>Rivera v. Wyeth-Ayerst Labs.</i> ,	
28	283 F.3d 315 (5th Cir. 2002) .....	10

1	<i>Robles v. Domino's Pizza, LLC.</i> ,	
2	913 F. 3d 898, (9th Cir. 2019) .....	22
3	<i>Rugg v. Johnson &amp; Johnson.</i> ,	
4	No. 17-cv-05010-BLF, 2019 U.S. Dist. LEXIS 2755, (N.D. Cal. Jan. 7, 2019).....	16
5	<i>S. Bay Chevrolet v. Gen. Motors Acceptance Corp.</i> ,	
6	72 Cal. App. 4th 861, (1999) .....	13
7	<i>Sandoval v. Mercedes-Benz USA, Inc.</i> ,	
8	2013 U.S. Dist. LEXIS 188997, (C.D. Cal. Sep. 24, 2013) .....	13
9	<i>Smith v. Allmax Nutrition, Inc.</i> ,	
10	No. 1:15-CV-00744-SAB, 2015 U.S. Dist. LEXIS 171897, 2015 WL 9434768, (E.D. Cal. Dec.	
11	24, 2015) .....	20
12	<i>Sotelo v. Rawlings Sporting Goods Co.</i> ,	
13	No. CV 18-9166-GW(MAAX), 2019 U.S. Dist. LEXIS 128163, (C.D. Cal. May 2, 2019) .....	16
14	<i>Swartz v. KPMG LLP.</i> ,	
15	476 F.3d 756, (9th Cir. 2007) .....	15
16	<i>Swearingen v. Santa Cruz Nat., Inc.</i> , No. 13-cv-04291-SI,	
17	2016 U.S. Dist. LEXIS 109432, (N.D. Cal. Aug. 17, 2016) .....	10
18	<i>Syntek Semiconductor Co., Ltd. v. Microchip Tech. Inc.</i> ,	
19	307 F.3d 775, (9th Cir. 2002) .....	21
20	<i>Tracton v. Viva Labs, Inc.</i> ,	
21	No. 16-cv-2772-BTM-KSC, 2017 U.S. Dist. LEXIS 151178, (S.D. Cal. Sep. 18, 2017) .....	13
22	<i>Trazo v. Nestlé USA, Inc.</i> ,	
23	No. 5:12-cv- 2272-PSG, 2013 U.S. Dist. LEXIS 113534, (N.D. Cal. Aug. 9, 2013) .....	22
24	<i>Vess v. Ciba-Geigy Corp. USA.</i> ,	
25	317 F.3d 1097, (9th Cir. 2003) .....	14
26	<i>Wallace v. ConAgra Foods, Inc.</i> ,	
27	747 F.3d 1025, 8th Cir. 2014) .....	12

28

1	<i>Watson v. Solid Gold Pet, LLC.</i> ,	
2	No. CV 18-6479 PSG (SSx), 2019 U.S. Dist. LEXIS 128123, (C.D. Cal. Feb. 22, 2019) .....	13
3	<i>Whitson v. Bumbo.</i> ,	
4	No. C 07-05597 MHP, 2009 U.S. Dist. LEXIS 32282 (N.D. Cal. Apr. 15, 2009) .....	10
5	<i>Wilson v. Hewlett-Packard Co.</i> ,	
6	668 F.3d 1136, (9th Cir. 2012) .....	13
7	<i>Zeiger v. WellPet LLC.</i> ,	
8	304 F. Supp. 3d 837, (N.D. Cal. 2018).....	10
9	<b>Statutes</b>	
10	21 U.S.C. § 342(a)(1).....	2
11	21 U.S.C. §349 .....	8
12	<b>Rules</b>	
13	Fed. R. Civ. P 9(b).....	14, 15
14	<b>Regulations</b>	
15	21 C.F.R. § 165.110(14)(i)-(ii) .....	17, 19
16	21 C.F.R § 165.110(a)(2)(vi).....	8
17	21 C.F.R § 165.110(a)(2)(6) .....	12
18	21 C.F.R § 165.110(c) .....	5
19	60 Fed. Reg. 57076-01, (FDA Nov. 13, 1995) .....	5, 9, 19



## INTRODUCTION

Plaintiff John Pels (“Plaintiff”) respectfully submits this memorandum in opposition to the Motion to Dismiss the Amended Class Action Complaint (“the Complaint” or “Cplt.”) filed by Defendant Keurig Dr. Pepper, Inc. (“Keurig” or “Defendant”).

This is a class action brought under California consumer law for damages, restitution, and injunctive relief stemming from Keurig’s sale for many years of Peñafiel mineral spring water that contains arsenic far above the legal limit. Plaintiff also seeks to represent a nationwide class of consumers to recover for unjust enrichment. In the wake of this action being brought, Keurig recalled the Peñafiel spring water line and *admitted its wrongdoing*. Nonetheless, Defendant has moved to dismiss the Complaint based on its refusal to accept its allegations as true, erroneous interpretations of state and federal law, and assertions in its brief (which are not in the Complaint and cannot be considered in a motion to dismiss) that all issues have been remediated, that no injunction is necessary, that it is in some sort of contact with the FDA justifying a stay due to primary jurisdiction, and that Plaintiff is neither entitled to damages nor restitution. As detailed herein, Defendant’s arguments are misconceived and misdirected, and in the end, mandate denial of its motion to dismiss.

Plaintiff will refer to two items for which Defendant requests judicial notice: (1) Defendant’s Ex. A, which is a label showing that a Peñafiel beverage of the type Plaintiff purchased bore the description “**Mineral Spring Water**” and (2) Defendant’s Ex. B, a *Consumer Reports* article dated June 28, 2019, entitled, “Arsenic Levels of Some Bottled Water Brands at Unsafe levels, Consumer Reports Says.” The *Consumer Reports* article contains testing that shows, of all national bottled water brands, only Peñafiel consistently exceeded state and federal arsenic limits by a wide margin, as recorded by both regulators and private laboratories. Indeed, Defendant imported Peñafiel water to the United States despite an FDA import ban.<sup>1</sup> Plaintiff also refers to two exhibits that are

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<sup>1</sup> Plaintiff is resubmitting this article with numbered paragraphs, to enable easier citation. See Jonckheer Decl., Ex. C. Defendant also offers as Ex. C to its Request for Judicial Notice its own press release dated June 21, 2019 concerning the product recall. Plaintiff does not oppose notice of those parts of that press release that contain admissions of historical facts, such that Keurig marketed a “violative” product. Plaintiff does object to any effort by Keurig to represent as true its press

appropriate for judicial notice: (1) a visual list of Peñafiel products taken from Keurig's website showing that Defendant labeled nine of fourteen Peñafiel beverages as "spring water",<sup>2</sup> and (2) FDA Import Alert 29-02, updated Aug. 16, 2019, which bans the import of Peñafiel carbonated water because it is adulterated.<sup>3</sup> See Plaintiff's Request for Judicial Notice ("Plts. RJN"), Sep. 9, 2019 & Declaration of Willem Jonckheer ("Jonckheer Decl."), Sep. 9, 2019, Exs. A & B.

### **FACTUAL ALLEGATIONS**

Defendant has known for many years that Peñafiel Mineral Spring Water was contaminated with high levels of arsenic in violation of federal law but chose to ignore the U.S. Food and Drug Administration's ("FDA's") regulations and import ban and sell it anyway. Cplt. ¶¶ 21-22. It was not until June 21, 2019 that Keurig belatedly issued a "withdrawal" of its arsenic-contaminated bottles of Mineral Spring Water. Cplt. ¶ 25. At that time, Keurig, having no real alternative, came clean and admitted that the product was "violative" of FDA arsenic limits. *Id.* Under FDA rules, if such water is sold, it must be labeled as "substandard." Cplt. ¶ 19. When recently tested by *Consumers Reports*, Peñafiel was the only water that was in material violation of FDA regulations. Cplt. ¶¶ 2-4. All other bottled waters, save one brand, were safely within FDA limits, and the vast majority contained little or no arsenic, as no reasonable consumer would purchase arsenic-laden water. *Id.*

Bottled water sales have expanded significantly, as consumers believe bottled water is healthy, unadulterated, and more flavorful in many cases than tap water. If the water has contaminants, there are established methods to remove such contaminants from the water to make it

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release statement that the unlawful arsenic levels posed no risk of harm, as this is an opinion that is contrary to the view of the FDA. See Plaintiff's Response to Defendant's Request for Judicial Notice, Sep. 9, 2019, pp. 2-3. As discussed *infra*, in FDA Import Alert 29-02, which pertains to Peñafiel beverages, the FDA described the Peñafiel products at issue in this case as "dangerous" and "adulterated." See Import Alerts and Enforcement, <https://www.fda.gov/food/metals/arsenic-food-and-dietary-supplements>.

<sup>2</sup> As discussed *infra*, "spring water" is subject to a special FDA regulation regarding its arsenic content. See *infra*, pp. 8-9.

<sup>3</sup> A food is adulterated if it contains any "poisonous or deleterious" substance, and the quantity of the substance (here, arsenic) ordinarily renders it "injurious to health." See 21 U.S. C. § 342(a)(1).

1 legally marketable and safe to drink. Keurig ignored the treatment option because treatment costs  
2 money, drives up costs, and cuts into profits. Cplt. ¶¶ 12-14.

3 Bottled water is subject to comprehensive federal and state government regulation. Producers  
4 of bottled water are responsible for assuring, through appropriate manufacturing techniques and  
5 sufficient quality control procedures, that all bottled water products introduced or delivered for  
6 introduction into interstate commerce comply with the 10 ppb [parts per billion] arsenic limitation  
7 and quality standard set forth in 21 C.F.R § 165.110(b)'s "Contaminant Chart." Moreover, any  
8 bottled water containing a substance at a level that causes the food to be "adulterated" under section  
9 402(a)(1) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 342(a)(1) (the "FDCA"), is  
10 subject to regulatory action, even if the bottled water bears a label statement of substandard quality.  
11 Cplt. ¶ 15. As 21 C.F.R. § 165.10(c)(3) makes clear, Peñafiel Spring Water—being contaminated  
12 with arsenic in excess of federal limits—was required to bear a label stating, "Contains Excessive  
13 Arsenic".

14 There are multiple reasons to regulate arsenic content in spring water. Arsenic is poisonous  
15 to humans and can cause serious health issues:

16 (a) **It damages the heart.** Young adults free of diabetes and cardiovascular disease  
17 developed heart damage after only five years of exposure to low-to-moderate levels of arsenic  
18 commonly found in groundwater;

19 (b) **It is a carcinogen.** It can cause lung cancer, bladder cancer, and skin cancer;

20 (c) **It can cause kidney disease.** Arsenic exposure can lead to chronic kidney disease, an  
21 irreversible condition for which there is no current treatment. Chronic kidney disease is progressive  
22 and leads to kidney failure; and

23 (d) **It increases the risk of diabetes.** Chronic arsenic exposure interferes with insulin  
24 secretion in the pancreas, which may increase the risk of diabetes. (Cplt. ¶ 18).

25 In 2015 and again in early 2018, the FDA issued import alerts entitled, "Detention Without  
26 Physical Examination of Bottled Water due to Arsenic." Among the producers listed was Peñafiel;  
27 the toxic products were identified as carbonated water (March 4, 2015) and mineral water (April 4,  
28 2018). Nonetheless, the issue persisted, and Keurig continued to import these dangerous products

1 into the United States unabated. Cplt. ¶ 22. The FDA recently renewed this ban. *See* Jonckheer Decl.  
2 Ex. B.

3 Plaintiff would not have purchased Peñafiel water had he known it was substandard. He  
4 “was deceived by Defendant in that he was of the belief he was obtaining a safe product made in  
5 conformity with the law.” Cplt. ¶ 19. Based on these allegations, Plaintiff asserts class claims under  
6 the CLRA, UCL, and FAL, and for unjust enrichment. Defendant’s actions violate the CLRA  
7 because its failure to conform Peñafiel water to the required safety standards is an unfair, deceptive,  
8 unlawful, and unconscionable commercial practice. Cplt. ¶¶ 38-45. It also failed to disclose  
9 Peñafiel’s “violative” arsenic levels, which exceeded federal (and identical state) standards, creating  
10 a safety hazard. Defendant’s conduct violates the unlawful and unfair prongs of the UCL because its  
11 sale of water containing excessive levels of arsenic violates FDA regulations and was unethical and  
12 injurious to California residents. Cplt. ¶¶ 46-60. Defendant’s conduct violates the FAL because  
13 Defendant advertises Peñafiel water in a manner that is untrue and misleading and that creates the  
14 impression that the product is safe to consume when, in fact, it is not. Cplt. ¶¶ 61-65. Based on these  
15 violations, Plaintiff, on behalf of the class, seeks injunctive relief, damages, and restitution.

### 16 17 SUMMARY OF ARGUMENT

18 This is an unusual motion to dismiss, as Keurig has publicly admitted to selling legally  
19 “violative” Peñafiel mineral spring water to consumers, as confirmed by its own testing. Cplt. ¶ 25.  
20 Defendant admitted on June 19, 2019 that it has broken FDA rules and that its product exceeded the  
21 legal limit of 10 ppb:

#### 22 **Keurig Dr Pepper Announces Voluntary Withdrawal of Unflavored Peñafiel** 23 **Mineral Spring Water that Does Not Meet FDA Bottled Water Quality** **Standards**

24 Keurig Dr Pepper today announced it will voluntarily withdraw Peñafiel unflavored  
25 mineral spring water products, imported from Mexico, *due to the presence of*  
26 *violative levels of arsenic*. Arsenic when present in the diet at very high levels, well  
27 above those detected in recent samples of Peñafiel, is associated with numerous  
28 chronic diseases. *Water quality tests of Peñafiel samples conducted by an*  
*independent laboratory on behalf of Keurig Dr Pepper detected arsenic at levels*  
*that exceeded the FDA’s bottled water standards for mineral water of 10 ppb.*

1 *Id.* and Declaration of Charles Sipos (“Sipos Decl.”), Ex. C (emphasis added). Despite these  
 2 extraordinary concessions—based on its own studies—Keurig has reversed itself. It now argues that  
 3 none of these things are true—or that Plaintiff has not properly alleged the very facts Keurig has  
 4 admitted.

5 First, despite arguing that its Peñafiel water brand is so pervasively regulated that primary  
 6 jurisdiction applies (Def’s Br. at 22-24),<sup>4</sup> Keurig simultaneously contends that Peñafiel is  
 7 unregulated and does not fall under the FDA’s arsenic limits because it is carbonated. Def’s Br. at  
 8 16-17. Keurig cannot have it both ways. The FDA does not agree that Peñafiel water (or any “spring  
 9 water”) is unregulated. In explaining the scope of the pertinent regulation, 21 CFR § 165.110  
 10 (“Section 165.110”), the FDA made clear that it covers ***any*** bottled water labeled “spring water”:

11 Products or ingredients described by a term that is defined by the standard of identity  
 12 (e.g., “spring water”) or with a term that makes a claim about the water (e.g., “natural  
 13 water”) are standardized waters and must comply with § 165.110 ***whether***  
***carbonation has been added or not.***

14 60 FR 57076, 57077 (emphasis added).<sup>5</sup> Because Keurig labels Peñafiel as “spring water,” it  
 15 falls within the FDA’s standard of identity for spring water. Keurig must therefore comply  
 16 with the FDA’s arsenic regulation, irrespective of added carbonation.

17 Moreover, the FDA’s repeated import bans of Peñafiel mineral spring water for excessive  
 18 arsenic contamination conclusively demonstrate that the product falls under the arsenic regulation.<sup>6</sup>  
 19 Most of Keurig’s remaining arguments are based on the faulty foundation and false assertion that  
 20 Peñafiel is not regulated and that its arsenic levels were not unlawful (despite its own description of  
 21 its product as “violative”). Accordingly, they should be disregarded.

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23 <sup>4</sup> All statements in Defendant’s brief as to any discussions it has or may have with the FDA—and all  
 24 of Keurig’s speculations as to what the FDA may do—are outside the Complaint and must be  
 25 disregarded at the motion to dismiss stage. Fed. R. Civ. P. 12(d); *see also Coverdell v. Dep’t of Soc.*  
*& Health Servs.*, 834 F.2d 758, 762 (9th Cir. 1987) (recitation of unsworn facts not evidence).

26 <sup>5</sup> The FDA’s interpretations are “controlling unless plainly erroneous or inconsistent with the  
 27 regulation[s]” or there is any other reason to doubt that they reflect the FDA’s fair and considered  
 28 judgment. *Auer v. Robbins*, 519 U.S. 452, 461-62 (1997).

<sup>6</sup> Bottled water that is of a quality below the prescribed standard required by § 165.110(c) must be  
 labeled with a statement of substandard quality. Here, there was no label statement, making this  
 failure a material omission.

1 The “violative” nature of the product wholly distinguishes Keurig’s principal authority,  
 2 *Boysen v. Walgreen Co.*, No. C 11-06262 SI, 2012 U.S. Dist. LEXIS 100528 (N.D. Cal. July 19,  
 3 2012), where plaintiff sought damages for the purchase of fruit juices that contained what the FDA  
 4 considered to be perfectly safe and acceptable levels of arsenic and lead. *Id.* at \*17 (“the FDA has  
 5 issued reports stating that the levels of lead and arsenic found in juice products such as defendant’s  
 6 are safe”).

7 Keurig’s contention that Plaintiff suffered no Article III “injury in fact” is no more  
 8 convincing. Plaintiff alleges he paid money for a product he believed was legal and safe but received  
 9 one that was unlawful and full of “violative” levels of toxic arsenic. He seeks restitution and  
 10 damages for purchasing a product he would have never purchased, let alone consumed, if it had been  
 11 properly labeled as “substandard.” A plaintiff satisfies the “injury in fact” requirement by alleging  
 12 that he bought a product when he “otherwise would not have done so.” *Reid v. Johnson & Johnson*,  
 13 780 F.3d 952, 958 (9th Cir. 2015) (quoting *Hinojos v. Kohl's Corp.*, 718 F.3d 1098, 1104 n.3 (9th  
 14 Cir. 2013)). Indeed, a “quintessential injury-in-fact” occurs when a plaintiff alleges that he “spent  
 15 money that, absent defendants’ actions, [he] would not have spent.” *Maya v. Centex Corp.*, 658 F.3d  
 16 1060, 1069 (9th Cir. 2011).<sup>7</sup>

17 Keurig also claims that Plaintiff is required to have done his own testing and cannot rely on  
 18 testing conducted by *Consumer Reports*. This argument is specious. In addition to the *Consumer*  
 19 *Reports* testing, Plaintiff relies on **Keurig’s own testing** and its admitted finding of “violative”  
 20 arsenic levels in the very product it marketed and sold to Plaintiff. *See* Cplt. ¶ 25. In addition,  
 21 Plaintiff has alleged that *all* Peñafiel mineral spring water during the Class Period was contaminated  
 22 with arsenic, obviating the need for Plaintiff either to test any bottles he has not already consumed or  
 23 to identify a specific purchase date. The contamination alleged here comes from the *source* of the  
 24 spring water. *See* Cplt. ¶ 5. This is not a case where arsenic was added to a particular lot or  
 25 production run. *See infra*, pp. 11-12. Rather, because the contamination originates from the source, it

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27  
 28 <sup>7</sup> Keurig is also incorrect that a consumer deception claim based on an unsafe product requires Plaintiff to plead and prove he suffered a physical injury. *See infra*, n.11.

1 is reasonable to infer that all Peñafiel water derived from that same contaminated source is itself  
2 contaminated.

3 Indeed, Keurig has asked this Court to take judicial notice of the *Consumer Reports* article,  
4 which recounts that violative arsenic levels were observed on a consistent basis by regulators  
5 beginning in 2008 and again in 2009, 2013, and 2014. Def. Ex. B. The FDA first issued its Import  
6 Alert banning Peñafiel in March 2015. Jonckheer Decl. Ex. B. Tellingly, Keurig's own admission  
7 that it would "voluntarily withdraw Peñafiel unflavored mineral spring water products, imported  
8 from Mexico, due to the presence of violative levels of arsenic" does not qualify the withdrawal  
9 (e.g., "certain," "some," or "select Peñafiel unflavored mineral spring water products"). Rather,  
10 Keurig issued a complete and total recall of its entire line of Peñafiel mineral spring water products.

11 Finally, Keurig seeks to escape liability based on speculation as to what the FDA may or  
12 may not do with respect to Peñafiel. This speculation—which is not contained in Plaintiff's  
13 complaint and thus must be ignored—supposedly undermines Plaintiff's request for an injunction  
14 and supports a stay under the primary jurisdiction doctrine. A statement made in a brief is entitled to  
15 no evidentiary weight and cannot form the basis of any action by this Court. *Cf. Coverdell v. Dep't*  
16 *of Soc. & Health Servs.*, 834 F.2d 758, 762 (9th Cir. 1987); *Bartholomew v. Finke*, No. 18-cv-  
17 04590-CRB, 2019 U.S. Dist. LEXIS 11080, at \*4 n.1 (N.D. Cal. Jan. 23, 2019) ("As this is a Motion  
18 to Dismiss, and statements made in a brief are not evidence, there is no reason to address this  
19 issue").

20 To even obtain a stay under the primary jurisdiction doctrine, Keurig must provide **evidence**  
21 that the FDA is in the process of addressing all or even some of the issues here. *See Pom Wonderful*  
22 *Ltd. Liab. Co. v. Ocean Spray Cranberries, Inc.*, 642 F. Supp. 2d 1112, 1123 (C.D. Cal. 2009). It  
23 has not done so. Nor has the FDA said or done anything concerning this litigation that would  
24 indicate it has any concerns about this case proceeding. *Cf. Hawyuan Yu v. Dr Pepper Snapple Grp.,*  
25 *Inc.*, No. 18-cv-06664-BLF, 2019 U.S. Dist. LEXIS 102023, at \*16-17 (N.D. Cal. June 18, 2019)  
26 (granting stay only where defendant submitted written statement from FDA confirming its intention  
27 to address the pertinent regulatory issues).



## ARGUMENT

### **I. Plaintiff Has Pled All Elements of a Consumer Law Violation.**

For many years, Keurig has sold unsuspecting consumers Peñafiel water that it knew through regular testing was laden with unlawful and (in the words of the FDA) “poisonous” levels of arsenic. It makes no apologies for this. Rather, it seeks to evade liability by arguing simultaneously that its product is unregulated and that it fears regulatory penalties. It also *admitted* its conduct was “violative” of FDA rules and that its imports exceeded the limit of 10 ppb—yet it claims Plaintiff has not properly alleged this. In sum, Keurig’s conduct is indisputably and admittedly illegal, deceptive, and unfair, supporting claims for UCL, CLRA, and FAL violations and providing a basis for recovery for unjust enrichment.

#### **A. Keurig Has Acted Unlawfully.**

It is unclear why Keurig argues it has not violated the law, when it has plainly admitted otherwise. Cplt. ¶ 25. Consumers who purchase bottled water believe that it is pristine, healthy, and stringently tested. Cplt. ¶ 14. In 1995, the FDA enacted a regulation limiting the allowed levels of arsenic in bottled waters, which is incorporated in 21 CFR § 165.110 (“Section 165.110”). Although the original tolerable arsenic level was set higher, the FDA reduced it to the current 10 ppb in 2005.<sup>8</sup> Keurig seizes on the fact that Peñafiel water is carbonated in an attempt to escape Section 165.110. While it is true that plain carbonated water used as an “ingredient” is not within the bottled water regulation, Peñafiel water is neither an “ingredient” nor plain carbonated water—rather, it bears the name “spring water”, which is a type of “bottled water,” as set forth in Section 165.110(a)(2)(vi). As “spring water”, Peñafiel water falls squarely within the bottled water arsenic limit. The FDA made this clear in 1995:

Two comments objected to the exclusion of carbonated bottled waters from the bottled water standards. They stated that any product that professes to be, or that has as an important ingredient that is one of the defined bottled water types (e.g., spring water, mineral water), whether noncarbonated or carbonated, should be considered to be bottled water. The comments contended that only those carbonated products with

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<sup>8</sup> 70 Fed. Reg. 33694, June 9, 2005, consistent with section 410 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 349).



respect to which no reference is made to defined bottled water types should be excluded.

***The agency agrees with the comment.***

Products or ingredients described by a term that is defined by the standard of identity (e.g., “spring water”) or with a term that makes a claim about the water (e.g., “natural water”) are standardized waters and must comply with § 165.110 ***whether carbonation has been added or not.***

60 FR 57076, 57077, note 3 (emphasis added)

Here, Peñafiel labeled nine of its fourteen water products as “spring water.” *See* Plaintiff’s RJN, Ex. A. Keurig was therefore legally prohibited from selling Peñafiel water, but it ignored this prohibition until sued by Plaintiff. Keurig also ignored the rule that violative bottled water be labeled “substandard” and contain the consumer warning “Contains Excessive Arsenic” under Section 165.110(c).

#### **B. Plaintiff Has Alleged Injury in Fact.**

Plaintiff believed he was buying a safe, legal product when in fact he was purchasing an unsafe, adulterated, mislabeled, toxic, “violative” product. This is hardly, as Keurig contends, receiving the “benefit of the bargain.” Plaintiff did not receive the benefit of the bargain, and as a result, he suffered economic injury. Keurig “induced him to buy products he would not otherwise have purchased.” *Hinojos v. Kohl’s Corp.*, 718 F.3d 1098, 1107 (9th Cir. 2013); *see also Chavez v. Blue Sky Natural Beverage Co.*, 340 F. App’x 359, 360-61 (9th Cir. 2009) (finding Article III standing where plaintiff “purchased beverages that he otherwise would not have purchased in absence of the alleged misrepresentations.”); *Brod v. Sioux Honey Ass’n, Co-op.*, 927 F. Supp. 2d 811, 820 (N.D. Cal. 2013), *aff’d*, 609 F. App’x 415 (9th Cir. 2015) (finding standing where the plaintiff alleged that the defendant violated its state law “duty to label Sue Bee Honey in a way that discloses the removal of pollen to potential consumers”); *Backus v. Gen. Mills*, 122 F. Supp. 3d 909, 920-21 (N.D. Cal. 2015) (where plaintiff purchased products that were allegedly detrimental to his health and were unfairly offered for sale in violation of law, he “has alleged a sufficient economic injury for standing under both Article III and the UCL”); *In re Morning Song Bird Food Litig.*, No. 12-cv-1592 JAH (RBB), 2013 U.S. Dist. LEXIS 149153, at \*9 (S.D. Cal. Sep. 30, 2013) (finding injury in fact where plaintiff would not have bought pesticide-laden bird food that was allegedly “not fit for consumption”).

1           Keurig relies heavily on this Court’s opinion in *Boysen v. Walgreen Co.*, No. C 11-06262 SI,  
 2   2012 U.S. Dist. LEXIS 100528, at \*22-24 (N.D. Cal. July 19, 2012). But, unlike here, in *Boysen* the  
 3   product (under then-current FDA rules) had arsenic levels that were “safe for consumption,” and  
 4   plaintiff “failed to allege noncompliance with applicable federal standards.” *Id.* at \*20. Indeed, this  
 5   Court recently distinguished *Boysen* where the product at issue, like the product now in question,  
 6   violated FDA guidelines. *Swearingen v. Santa Cruz Nat., Inc.*, No. 13-cv-04291-SI, 2016 U.S. Dist.  
 7   LEXIS 109432, at \*10-11 n.1 (N.D. Cal. Aug. 17, 2016) (Illston, J.).<sup>9</sup>

8           Keurig’s other authorities fare no better. *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315 (5th  
 9   Cir. 2002), is not on point at all. There, plaintiff sued for damages despite his concession that the  
 10   medicine at issue caused damages to patients only if *misused*—but plaintiff had not misused it. *Id.* at  
 11   317, 319-20 (finding plaintiff was admittedly “not among the injured”). Nor did plaintiff allege that  
 12   anyone ingesting the substance might suffer any future health consequences. *Id.* at 317. Finally, the  
 13   medicine, Duract, was never illegal because it was safe if used as directed; it was withdrawn from  
 14   the market only because it was subject to misuse. *Id.* Similarly, *Lassen v. Nissan N. Am., Inc.*, 211 F.  
 15   Supp. 3d 1267, 1283 (C.D. Cal. 2016), involved a perfectly legal automobile that complied with all  
 16   safety standards and had no “design defect.” Plaintiff could not plead injury because he sued  
 17   defendant for failing to include a device that would protect plaintiff from his own possible human  
 18   error in forgetting to turn off the vehicle after parking. *Id.* at 1283 (holding defendant could not be  
 19   held liable simply because “drivers neglect to press the start/stop button to stop the vehicle’s  
 20   engine.”). *Whitson v. Bumbo*, No. C 07-05597 MHP, 2009 U.S. Dist. LEXIS 32282 (N.D. Cal. Apr.  
 21   15, 2009), involved a product plaintiff never used and never had an issue with; she could not sue  
 22   because a few others ran into difficulties.<sup>10</sup>

23           The prevailing rule is that where, as here, a plaintiff buys a product expecting it to meet a  
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25   <sup>9</sup> See also *Zeiger v. WellPet LLC*, 304 F. Supp. 3d 837, 846 (N.D. Cal. 2018) (distinguishing *Boysen*  
 26   and upholding injury claim where the FDA had not determined that the product’s arsenic levels were  
 safe).

27   <sup>10</sup> *Nguyen v. Biter*, No. 1:11-cv-00809-AWI-SKO (PC), 2015 U.S. Dist. LEXIS 119406 (E.D. Cal.  
 28   Sep. 7, 2015), was not a consumer action, but rather a civil rights action in which a prisoner failed at  
 summary judgment to produce expert evidence supporting his claims.

certain standard, he is entitled to money damages or restitution if that product falls short. *See Dana v. Hershey Co.*, 180 F. Supp. 3d 652, 662 n.8 (N.D. Cal. 2016). Appropriate restitution warrants a full refund “when the plaintiffs prove the product had *no* value to them.” *Chowning v. Kohl’s Dep’t Stores, Inc.*, 733 F. App’x 404, 406 (9th Cir. 2018) (citation omitted). Here, had Keurig told the truth, Plaintiff would not have paid anything for adulterated Peñafiel water.<sup>11</sup>

**C. Plaintiff’s Damages and Restitution Claims Are Not Moot.**

Keurig’s “refund” offer as to bottles that may be returned offers too little, too late, as it provides nothing to Plaintiff or Class members like him who bought and *consumed* toxic bottles of Peñafiel water over several years. Thus, Keurig errs in asserting it has provided Plaintiff and the Class “the same relief” sought through litigation. Def’s Br. at 14. Like all such bottled water, Peñafiel bottled water has been purchased, consumed, discarded or recycled for many years, and only a small fraction of bottles sold during the Class Period will have been retained by Class members. Keurig’s offer assumes consumers purchased its adulterated products and placed them on a shelf, where they have remained since the purchase date.

Keurig’s remedial actions are wholly inadequate, as they are limited to customers who still have the “product in their possession.” Sipos Decl., Ex. C. This falls far short of the full refund for all purchased bottles that Plaintiff seeks, as he and other Class members have not retained all the water they ever purchased. *See* Cplt. ¶¶ 6, 44, 52, 60. Plaintiff’s claims are not moot where a refund offer “covers only a portion of Plaintiff’s purported damages.” *Haddix v. Gen. Mills, Inc.*, No. 2:15-cv-02625-MCE-AC, 2016 U.S. Dist. LEXIS 65108, at \*16 (E.D. Cal. May 17, 2016).

**D. Plaintiff Did Not Need to Allege a Specific Purchase Date.**

Keurig, in asserting that Plaintiff did not allege his Peñafiel water bottles were contaminated by arsenic, relies upon a line of cases in which a production line error led to some lots being contaminated and others not. But the “some are, some are not” issue does apply to this type of

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<sup>11</sup> There is no requirement of physical injury in such instances. *See, e.g., In re Hydroxycut Mktg. & Sales Practices Litig.*, 801 F. Supp. 2d 993, 1002-05 (S.D. Cal. 2011) (“Plaintiffs sought to purchase a safe and effective weight loss product but did not receive the product as promised. As a result, they have lost the money they paid for the product and have alleged an economic injury.”) (collecting cases that held no physical injury need be pled).

“spring water,” which is drawn from a ground source and is contaminated *at the source*.<sup>12</sup> Thus, as discussed above, Keurig’s recall naturally extended to *all* of its Peñafiel water (Cplt ¶ 25); it was not confined to any specific lots or production runs. *See* Def’s RJN Ex. C, p.1 (recall relates to “all” Peñafiel water). Likewise, the FDA Import Alert (reiterated on Aug. 16, 2019) applies to *all lots*. *See* Jonckheer Decl., Ex. B. In these circumstances, Plaintiff’s allegation that his claim and that of the Class encompass *all bottles* suffices.<sup>13</sup>

Nor can Keurig’s rank speculation—not contained in the Complaint—that Plaintiff may have purchased outside the contamination period defeat the well-pleaded allegations in the Complaint. Here, Plaintiff alleges that the contamination dates back at least a decade, that the Class Period is coterminous with the statute of limitations period, and that Plaintiff is a Class member who purchased during the Class Period. Cplt ¶¶ 11, 28-29, 33. This is sufficient. Indeed, courts in this District routinely find that a plaintiff has pleaded sufficient facts concerning his purchase date when the complaint alleges that the plaintiff made his purchase during the class period. *See, e.g., Clancy v. The Bromley Tea Co.*, 308 F.R.D. 564, 576 (N. D. Cal. 2013); *Bruton v. Gerber Products Co.*, No. 12-cv-2412-LHK, 2014 U.S. Dist. LEXIS 5493, at \*13 (N.D. Cal. Jan. 15, 2014); *Ang v. Bimbo Bakeries USA, Inc.*, No. 13-cv-1196-WHO, 2013 U.S. Dist. LEXIS 138897, at \*2-3 (N.D. Cal. Sept. 25, 2013).

#### **E. Plaintiff Has Adequately Pled Reliance.**

Keurig failed to disclose that Peñafiel water contained arsenic. Keurig also failed to obey FDA labeling requirements that require a warning to consumers. For an omission to be actionable under the CLRA or UCL, it must either be “contrary to a representation actually made by the

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<sup>12</sup> Section 165.110(a)(2)(6): “The name of water derived from *an underground formation from which water flows naturally to the surface of the earth* may be ‘spring water.’ Spring water shall be collected *only at the spring* or through a bore hole tapping the underground formation feeding the spring.” (emphasis added).

<sup>13</sup> The situation was different in *Wallace v. ConAgra Foods, Inc.*, 747 F.3d 1025, 1029-30 (8th Cir. 2014) relied upon by Keurig, where most of the product sold was unaffected by the issue plaintiff raised. *Cf. Organic Consumers Ass’n v. General Mills, Inc.*, 2017 D.C. Super. LEXIS 4, \*15-17 (D. D.C. July 6, 2017)(distinguishing *Wallace* where plaintiffs had cause to allege that *all* products contained the harmful chemical glyphosate).

defendant, or an omission of a fact the defendant was obligated to disclose.” *Sandoval v. Mercedes-Benz USA, Inc.*, 2013 U.S. Dist. LEXIS 188997, at \*41 (C.D. Cal. Sep. 24, 2013). Where an omission concerns a safety issue with the product, a defendant is obligated to disclose the safety issue to consumers. *See Hodsdon v. Mars, Inc.*, 891 F.3d 857, 864 (9th Cir. 2018); *Wilson v. Hewlett-Packard Co.*, 668 F.3d 1136, 1143 (9th Cir. 2012).

Here, Keurig failed to disclose that its Peñafiel water contained “violative” levels of arsenic in contravention of FDA regulations (and identical California regulations), which, in the FDA’s opinion, pose a safety risk to consumers. *See* Cplt. ¶ 22; Plaintiffs’ RJN, Ex. B. In these circumstances, courts have been particularly critical of failures to clearly warn of the dangers of products intended to be ingested as a food or supplement. *See, e.g., Watson v. Solid Gold Pet, LLC*, No. CV 18-6479 PSG (SSx), 2019 U.S. Dist. LEXIS 128123, at \*13-14 (C.D. Cal. Feb. 22, 2019) (finding duty to disclose presence of heavy metals and other dangerous ingredients in pet food; defendant “knew that this information was important for the consumers”); *Kellman v. Whole Foods Mkt., Inc.*, 313 F. Supp. 3d 1031 (N.D. Cal. 2018) (denying motion to dismiss UCL, FAL, and CLRA claims where body care products concealed presence of known allergens); *Lewis v. Rodan & Fields, LLC*, No. 18-cv-02248-PJH, 2019 U.S. Dist. LEXIS 32470, at \*9 (N.D. Cal. Feb. 28, 2019) (“the court finds that plaintiffs have plausibly alleged an omission-based false advertising claim premised on defendant’s failure to disclose the potential side effects associated with the product by virtue of it containing [dangerous ingredient] ICP.”).<sup>14</sup>

To satisfy reliance on an omission with respect to consumer claims, a plaintiff need only allege “that the defendant’s nondisclosure was an immediate cause of the plaintiff’s injury-producing conduct.” *Daniel v. Ford Motor Co.*, 806 F.3d 1217, 1225 (9th Cir. 2015). “A plaintiff

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<sup>14</sup> Even if there was no duty to disclose its omissions, Keurig’s conduct may nonetheless be actionable if it was “unfair” under the UCL. *Hodsdon v. Mars, Inc.*, 891 F.3d 857, 865-66 (9th Cir. 2018) (“Unlike the other two UCL prongs, the lack of a duty to disclose does not necessarily dispose of claims under the unfair prong.”). A defendant’s practices “are considered unfair if the utility of its conduct is outweighed by the gravity of the harm that a plaintiff allegedly suffers.” *Tracton v. Viva Labs, Inc.*, No. 16-cv-2772-BTM-KSC, 2017 U.S. Dist. LEXIS 151178, at \*23 (S.D. Cal. Sep. 18, 2017) (citing *S. Bay Chevrolet v. Gen. Motors Acceptance Corp.*, 72 Cal. App. 4th 861, 886-87 (1999)) (adopting “balancing” test).

1 may do so by simply proving that, had the omitted information been disclosed, one would have been  
 2 aware of it and behaved differently. That one would have behaved differently can be presumed, or at  
 3 least inferred, when the omission is material.” *Id.* (internal citations and quotation marks omitted);  
 4 *see also Jordan v. Paul Fin., LLC*, 745 F. Supp. 2d 1084, 1096 (N.D. Cal. 2010) (Illston, J.). Here,  
 5 Plaintiff easily satisfies this reliance requirement.

#### 6 **F. Plaintiff’s Plead Their Claims with Sufficient Specificity.**

7 Although fraud-based claims must be plead with greater particularity pursuant to Rule 9(b),  
 8 Plaintiff’s UCL claims are based on the unlawful and unfair prongs of the UCL and should be  
 9 assessed pursuant to Rule 8’s pleading standards. *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097,  
 10 1105 (9th Cir. 2003) (“Allegations of non-fraudulent conduct need satisfy only the ordinary notice  
 11 pleading standards of Rule 8(a).”). Fraud is not an essential element of a claim for unfair or  
 12 unlawful business practices, and Plaintiff’s UCL claims do not sound in fraud. Rather, they are  
 13 based on Defendant’s violation of FDA regulations. Cplt. ¶¶ 49, 56-58; *see also Campen v. Frito-*  
 14 *Lay N. Am., Inc.*, No. 12-1586 SC, 2013 U.S. Dist. LEXIS 47126 at \*13 (N.D. Cal. Apr. 1, 2013)  
 15 (“the rule is that plaintiffs need not satisfy Rule 9(b) as to the UCL’s unlawful prong when the basis  
 16 of their claim does not sound in fraud”); *Clark v. WorldMark*, No. 1:18-cv-01661-LJO-JLT, 2019  
 17 U.S. Dist. LEXIS 124445, at \*19 (E.D. Cal. July 25, 2019) (“Plaintiffs’ claims under the ‘unlawful’  
 18 prong of the UCL are not entirely grounded in fraud and need not be plead with particularity.”);  
 19 *Goodman v. HTC Am., Inc.*, No. C11-1793MJP, 2012 U.S. Dist. LEXIS 88496, at \*34 (W.D. Wash.  
 20 June 26, 2012) (applying heightened pleading standard to UCL fraud prong but not unlawful or  
 21 unfair prongs).

22 Even as to those elements of his claim where deception is required, Plaintiff adequately  
 23 alleges that he was deceived by Defendant. *See* Cplt. ¶ 11. Plaintiff’s allegation is bolstered by the  
 24 obvious materiality of toxic arsenic levels—an element that is poisonous to humans and can cause a  
 25 litany of serious health conditions, such as heart damage, cancer, kidney disease, and diabetes. Cplt.  
 26 ¶ 18.

27 In sum, because Keurig’s omissions are *per se* material, Plaintiff’s allegations are sufficient  
 28 to meet Rule 8’s and Rule 9(b)’s pleading standards. Furthermore, the particularity required in



1 pleading fraud is not intended to be mechanically applied. Rather, the facts alleged must merely “be  
2 enough to give defendant notice of the particular misconduct which is alleged to constitute the fraud  
3 charged so that they can defend against the charge and not just deny that they have done anything  
4 wrong.” *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007).

5 **G. Plaintiff Adequately Alleges Keurig’s Knowledge of Illegal Arsenic Levels.**

6 Keurig argues that Plaintiff has failed to allege that it was aware of Peñafiel’s “violative”  
7 arsenic levels at the time of sale. Not so. Plaintiff specifically alleges that Peñafiel was subject to  
8 FDA import alerts in 2015 and 2018 and during the relevant period had an ongoing testing  
9 requirement under the law. Cplt. ¶¶ 19, 22. Plaintiff further alleges that under federal (and identical  
10 state) standards, Keurig was required to ensure that its bottled water contained arsenic levels no  
11 higher than 10 ppb. Cplt. ¶ 19. Yet, according to water quality tests conducted by Keurig, it  
12 confirmed previous reliable reports of arsenic levels far in excess of the FDA’s bottled water  
13 standards. Cplt. ¶ 25. Under Rule 9(b), knowledge “may be averred generally.” *Odom v. Microsoft*  
14 *Corp.*, 486 F.3d 541, 553 (9th Cir. 2007). At this stage, Plaintiff’s allegations are more than  
15 sufficient to satisfy this standard.

16 **H. Plaintiff Has Standing to Seek an Injunction.**

17 Keurig appears to argue that Plaintiff could only have Article III standing to pursue  
18 injunctive relief if he declares his intention to purchase Keurig’s adulterated water “as is,”  
19 presumably with excessive arsenic included. Def’s Br. at 14. There is no such rule of law. Keurig  
20 relies primarily on *Hawyuan Yu v. Dr Pepper Snapple Grp., Inc.*, No. 18-cv-06664-BLF, 2019 U.S.  
21 Dist. LEXIS 102023, at \*14 (N.D. Cal. June 18, 2019), but there, the plaintiff stated that he would  
22 *never* buy the product at issue, even if the issues he complained about were fixed. That is not the  
23 case here, as Plaintiff says he will resume his purchases once he is assured the arsenic problem is  
24 conclusively addressed. Cplt ¶ 11.

1 This is all that a Plaintiff need aver to establish standing for injunctive relief.<sup>15</sup> In *Davidson*  
 2 *v. Kimberly-Clark Corp.*, the Ninth Circuit clarified the standard for Article III standing for  
 3 injunctive relief concerning a consumer product:

4 We hold that a previously deceived consumer may have standing to seek an  
 5 injunction against false advertising or labeling, even though the consumer now  
 6 knows or suspects that the advertising was false at the time of the original purchase,  
 7 because the consumer may suffer an “actual and imminent, not conjectural or  
 8 hypothetical” threat of future harm. ... Knowledge that the advertisement or label was  
 9 false in the past does not equate to knowledge that it will remain false in the future. In  
 10 some cases, the threat of future harm may be the consumer’s plausible allegations  
 11 that she will be unable to rely on the product’s advertising or labeling in the future,  
 12 and so will not purchase the product although she would like to. ... In other cases,  
 13 **the threat of future harm may be the consumer’s plausible allegations that she**  
 14 **might purchase the product in the future, despite the fact it was once marred by**  
 15 **false advertising or labeling, as she may reasonably, but incorrectly, assume the**  
 16 **product was improved.**

17 889 F.3d 956, 969-70 (9th Cir. 2018) (emphasis added).

18 Plaintiff’s allegations in the Complaint plainly meet this standard. Plaintiff avers that he will  
 19 resume his purchases once he is assured the arsenic problem is conclusively addressed. Cplt. ¶ 11.  
 20 This is sufficient. *See, e.g., Sotelo v. Rawlings Sporting Goods Co.*, No. CV 18-9166-GW(MAAX),  
 21 2019 U.S. Dist. LEXIS 128163, at \*10-12 (C.D. Cal. May 2, 2019) (finding standing to seek  
 22 injunction as to defendant’s sports products, even though the product plaintiff bought would not be  
 23 remarketed in that exact form); *Rugg v. Johnson & Johnson*, No. 17-cv-05010-BLF, 2019 U.S. Dist.  
 24 LEXIS 2755, at \*9 (N.D. Cal. Jan. 7, 2019) (finding standing for injunctive relief where, absent such  
 25 relief, plaintiff would have no way of ensuring herself in the future that the products were actually  
 26 hypoallergenic, as claimed); *Arabian v. Organic Candy Factory*, No. 2:17-cv-05410-ODW-PLAX,  
 27 2018 U.S. Dist. LEXIS 45833, 2018 WL 1406608 (C.D. Cal. Mar. 19, 2018) (finding standing for  
 28 injunctive relief where plaintiff alleged an intent to purchase a snack product in the future and an  
 inability to know whether the product would contain represented ingredients in the future).

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<sup>15</sup> *Gonzalez v. Costco Wholesale Corp.*, No. 16-CV-2590 (NGG) (JO), 2018 U.S. Dist. LEXIS 171000 (E.D.N.Y. Sep. 29, 2018), is not germane, as it was decided under Second Circuit law which is presently unsettled. The opposite conclusion was reached in that same district in *Kurtz v. Kimberly-Clark Corp.*, 321 F.R.D. 482, 491 (E.D.N.Y. 2017).



Finally, Keurig asserts that Plaintiff's claims for injunctive relief are moot based on its assertion—not contained in the Complaint—that Keurig “implemented enhanced filtration at its Mexico plant.” Def's Br. at 14. Because these facts are not contained in the Complaint, Keurig's unverified assertions about remedial actions it may have taken to address its illegal conduct cannot be taken as true in a motion to dismiss. Fed. R. Civ. P. 12(d). Nonetheless, even if Keurig had implemented such measures, they would not moot Plaintiff's claims. Whether these purported remedial measures adequately resolve the toxic levels of arsenic contained in Peñafiel water is a question of fact not suitable to a motion to dismiss. *Beliveau v. Caras*, 873 F.Supp. 1393, 1399 (C.D. Cal. 1995) (“The Court cannot make factual determinations on a motion to dismiss; rather, the inquiry is whether the facts as alleged are sufficient to state a claim”). Moreover, any voluntary steps Keurig may have taken to address these issues are not an adequate substitute for a permanent injunction, especially here, where the “the alleged threatened injury is sufficiently likely to recur” absent an injunction. *Mayfield v. United States*, 599 F.3d 964, 970 (9th Cir. 2010). Keurig's mootness argument is therefore premature.

## II. Keurig's Preemption Argument Is Procedurally Premature and Substantively Flawed.

Keurig's express preemption argument is not premised on any conflicting state law but rather the specific method and manner of arsenic testing alleged in Plaintiff's complaint. In essence, Keurig argues that (1) Plaintiff has a mandatory, pre-suit requirement to test Peñafiel Water pursuant to 21 C.F.R. § 165.110(14)(i)-(ii) prior to bringing claims under California's consumer protection statutes and (2) that Plaintiff, in his pleadings, must prove that the level of arsenic contained in Peñafiel Water exceeds FDA standards in accordance with FDA testing methodology. This argument is conclusively answered by Keurig's *own admission* that it independently tested its product and found it contained levels of arsenic that were “violative” of FDA limits. Cplt. ¶ 25. Plaintiff needs to cite to nothing more. This violative result confirms previous regulatory testing. Cplt. ¶¶ 3, 21-22.

But even if Keurig had made no such admission, Plaintiff need not demonstrate conformity

1 with the FDA's testing methodology to plead claims under California's consumer protection  
 2 statutes. *See, e.g., Gubula v. CVS Pharm., Inc.*, No. 14 C 9039, 2016 U.S. Dist. LEXIS 32759 at \*27  
 3 (N.D. Ill. Mar. 15, 2016). In any event, Plaintiff has pled that Peñafiel Water contains toxic levels of  
 4 arsenic in accordance with testing done by the FDA (or which was submitted to it by sources it  
 5 trusted). Cplt. ¶¶ 22, 25.

6 Preemption analysis begins with a presumption against preemption. *Cipollone v. Liggett*  
 7 *Group, Inc.*, 505 U.S. 504, 516, (1992). FDCA preemption, like all federal preemption, is an  
 8 affirmative defense. *Lusnak v. Bank of Am. N.A.*, 883 F.2d 1185, 1194, n.6 (9th Cir. 2018). "Only  
 9 when the plaintiff pleads itself out of court—that is, admits all the ingredients of an impenetrable  
 10 defense— may a complaint that otherwise states a claim be dismissed under Rule 12(b)(6)."  
 11 *Durnford v. MusclePharm Corp.*, 907 F.3d 595, 603 n.8 (9th Cir. 2018) (quoting *Xechem, Inc. v.*  
 12 *Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004)).

13 Keurig places great reliance on *Durnford*, but plaintiff there argued that the FDA's standards  
 14 and methodology were wrong and attempted to supplant them with entirely different methodologies  
 15 and standards. The Ninth Circuit understandably rejected the plaintiff's attempt to change the FDA  
 16 rules. *Durnford*, 907 F.3d at 601-02. Likewise, in *Salazar v. Honest Tea, Inc.*, 74 F. Supp. 3d 1304,  
 17 1313 (E.D. Cal. 2014), plaintiff attempted to twist FDA rules, which allowed nutrient content to be  
 18 measured on an *average* basis, by insisting that the product must meet the standard on a *per item*  
 19 basis. Plaintiff did not even attempt to show that any FDA rules were violated, nor did the company  
 20 admit any violation. Similarly, *Mee v. I A Nutrition, Inc.*, No. C-14-5006 MMC, 2015 U.S. Dist.  
 21 LEXIS 63038, at \*10-12 (N.D. Cal. May 13, 2015), did not involve a defendant's own admission of  
 22 FDA violations. Rather, in *Mee*, plaintiff submitted his own testing, which involved a different  
 23 standard than the FDA's. *Id.* at \*7-8.

24 Defendant also relies on *In re: Whole Foods Market Inc.*, 163 F. Supp. 3d 385 (W.D. Tex.  
 25 2016), for its assertion that preemption is warranted where an FDA regulation establishes testing  
 26 methodology. The case is easily distinguishable. In *Whole Foods Market*, the defendant had not  
 27 conducted its own testing or admitted it found violations. Plaintiffs there also did not allege that  
 28 their testing conformed with FDA regulations; rather, they "expressly [pled] that *Consumer Reports*

1 used a different testing methodology,” which was more burdensome than that provided under the  
 2 FDCA. *Id.* at 393.<sup>16</sup> By contrast, here Plaintiff makes no such allegation; he pleads that Peñafiel  
 3 contains toxic levels of arsenic violative of FDA limits, ***both as reported by the FDA and admitted***  
 4 ***by Defendant.*** Cplt. ¶¶ 22, 25.

5 Defendant also fails to identify how the additional (non-Keurig) testing alleged by Plaintiff  
 6 differs from FDA requirements. Its motion does not identify any portions of Plaintiff’s complaint  
 7 that describe testing that in any way differs from FDA regulations. Yet even if Keurig could identify  
 8 any differences between *Consumer Reports* and the FDA’s testing protocols, its argument that  
 9 Plaintiff must employ and plead the exact same testing protocol as 21 C.F.R. § 165.110(14)(i)-(ii) to  
 10 avoid preemption is incorrect. Rather, a testing protocol need only be sufficiently equivalent to FDA  
 11 methods. *See Beverages: Bottled Water*, 60 Fed. Reg. 57076-01, 57120 (FDA Nov. 13, 1995) (“[I]f  
 12 the State requirement does the same thing that the Federal law does ... then it is effectively the same  
 13 requirement as the Federal requirement. ... [T]he only State requirements that are subject to  
 14 preemption are those that are affirmatively different from the Federal requirements.”). The FDA has  
 15 relaxed its testing protocol so that private laboratories may be used, and these laboratories can  
 16 employ any ***reliable*** method: “FDA does not endorse any private laboratory firms, nor requires  
 17 specific methods to be used for [Private Laboratory Analytical Packages]. Methods link[ed] herein  
 18 are provided as a courtesy, ***but private laboratories are not required to use them.*** The collected  
 19 sample(s) should be analyzed using appropriate methods that have been properly validated.” U.S.  
 20 Food & Drug Administration, *Private Laboratory Testing*, [https://www.fda.gov/science-](https://www.fda.gov/science-research/field-science-and-laboratories/private-laboratory-testing)  
 21 [research/field-science-and-laboratories/private-laboratory-testing](https://www.fda.gov/science-research/field-science-and-laboratories/private-laboratory-testing) (May 15, 2019) (emphasis added).

22 Even ignoring Keurig’s own admissions and the adverse FDA actions, Plaintiff’s allegations  
 23 concerning third-party testing are sufficient. *See Clay v. Cytosport, Inc.*, No. 15-CV-165 L DHB,  
 24 2015 U.S. Dist. LEXIS 110447, at \*9 (S.D. Cal. Aug. 19, 2015); *Gubula v. CVS Pharm., Inc.*, No.

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26 <sup>16</sup> In fact, in *Whole Foods Market*, the Court made clear that it did not intend for its ruling to  
 27 establish a new pleading requirement: “The Court need not decide whether, in all cases, alleging the  
 28 precise testing methodology is a pleading requirement because the SACC affirmatively alleges  
*Consumer Reports* did not follow the applicable protocols.” 163 F. Supp. 3d at 393-94.

1 14 C 9039, 2016 U.S. Dist. LEXIS 32759 at \*27 ((N.D. Ill. Mar. 15, 2016); *Smith v. Allmax*  
 2 *Nutrition, Inc.*, No. 1:15-CV-00744-SAB, 2015 U.S. Dist. LEXIS 171897, 2015 WL 9434768, at \*7  
 3 (E.D. Cal. Dec. 24, 2015) (“Based upon the allegations in the complaint, the Court can plausibly  
 4 infer that tests conducted in compliance with [FDA] methodology would supply [p]laintiff’s  
 5 allegations that the Product is mislabeled.”).

6 In *Gubula*, for example, plaintiff attached to his complaint a single test on a single sample of  
 7 protein powder, where the FDA regulations required sample nutrient analysis on a composite of  
 8 twelve subsamples, taken one from each of twelve different, randomly chosen, shipping cases.  
 9 *Gubula*, U.S. Dist. LEXIS 32759 at \*24. The Court acknowledged that plaintiff’s testing was  
 10 noncompliant with the FDA regulations, but it nonetheless rejected defendant’s preemption  
 11 argument and denied its motion to dismiss, finding independent testing in conformance with the  
 12 regulations would remain an issue of proof going forward and that plaintiff need not prove his case  
 13 at the pleading stage. *Id.* at \*27.

14 Similarly, in *Clay*, plaintiff alleged that defendant’s protein supplements violated California  
 15 consumer protection statutes based on testing conducted by labdoor.com and an “independent”  
 16 source of testing. *Clay*, 2015 U.S. Dist. LEXIS 110447, at \*6. Defendant moved to dismiss, arguing  
 17 that plaintiffs’ claims were preempted because they did not employ the testing methodology  
 18 mandated by the FDA. *Id.* The Court rejected defendant’s argument, finding that it was “not  
 19 appropriate for a motion to dismiss.” *Id.* at \*10. The court recognized that, “in order to ultimately  
 20 prevail on these claims, Plaintiffs will have to prove that Defendant did not comply with the FDCA  
 21 provision” but found that “to state a claim, Plaintiffs only need to allege a plausible violation of the  
 22 FDCA.” *Id.*

23 Here, Plaintiff has presented ample evidence to support a plausible violation of the FDCA.  
 24 Plaintiff alleges that numerous tests conducted by various parties between 2009 and 2019 (including  
 25 by Keurig itself) indicate that Peñafiel contains high levels of arsenic in violation of the FDA’s  
 26 bottled water standards. Cplt. ¶¶ 21-23, 25. Indeed, Keurig itself admitted that the levels were  
 27 “violative” of the FDA regulations. Moreover, Plaintiff alleges that the FDA issued import alerts on  
 28 Peñafiel in 2015 and 2018 due to toxic arsenic levels. Cplt. ¶ 22. And Plaintiff quotes Keurig’s own

1 press release, which admits that the company withdrew the water “due to the presence of violative  
 2 levels of arsenic” that “exceeded the FDA’s bottled water standards for mineral water.” Cplt. ¶ 25.  
 3 This is more than enough at the pleading stage.

### 4 **III. The Primary Jurisdiction Doctrine Is Inapplicable.**

#### 5 **A. Keurig Presents No Evidence to Support Primary Jurisdiction.**

6 The Complaint does not plead anything that would justify the application of the primary  
 7 jurisdiction doctrine. In its motion, Keurig improperly attempts to introduce unsworn factual  
 8 assertions. This is insufficient. Keurig’s assertions in its motion are contrary to the allegations in  
 9 Plaintiff’s complaint and must be disregarded. *See Coverdell*, 834 F.2d at 762. Keurig claims: (1)  
 10 that it is in discussions with the FDA; (2) that such discussions relate in some way to the relief  
 11 sought in this action; and (3) that it has undertaken complete and lasting remedial measures. One  
 12 basis Keurig invokes for primary jurisdiction is clearly speculation: it supposedly fears (even though  
 13 it claims it is not regulated) that it may face regulatory penalties that overlap the remedies sought  
 14 herein. Keurig’s rank speculation should be disregarded. It presents no basis to believe that the FDA  
 15 has done or may do anything that will affect this action. Accordingly, Keurig’s attempt to invoke  
 16 primary jurisdiction should be rejected.

#### 17 **B. Keurig Fails to Meet the High Threshold for Primary Jurisdiction.**

18 Even if Keurig had presented evidence this Court could consider, the primary jurisdiction  
 19 doctrine is only appropriate “in a limited set of circumstances.” *Clark v. Time Warner Cable*, 523  
 20 F.3d 1110, 1114 (9th Cir. 2008). It permits a court to stay a case or to dismiss it without prejudice  
 21 “pending the resolution of an issue within the special competence of an administrative agency.” *Id.*  
 22 The doctrine is “used only if a claim requires resolution of an issue of first impression, or of a  
 23 particularly complicated issue that Congress has committed to a regulatory agency” but not “every  
 24 time a court is presented with an issue conceivably within the agency’s ambit.” *Id.* Thus, it “is a  
 25 prudential doctrine under which courts may, under appropriate circumstances, determine that the  
 26 initial decision making responsibility should be performed by the relevant agency rather than the  
 27 courts.” *Syntek Semiconductor Co., Ltd. v. Microchip Tech. Inc.*, 307 F.3d 775, 780 (9th Cir. 2002).  
 28 However, the primary jurisdiction doctrine should not be applied where the plaintiff’s claims are

1 “within the conventional competence of the courts.” *Nader v. Allegheny Airlines, Inc.*, 426 U.S. 290,  
2 305 (1976).

3 The Ninth Circuit makes clear that “efficiency” is the “deciding factor” in the application of  
4 this doctrine and that “primary jurisdiction is not required when a referral to the agency would  
5 significantly postpone a ruling that a court is otherwise competent to make.” *Robles v. Domino’s*  
6 *Pizza, LLC*, 913 F. 3d 898, 910 (9th Cir. 2019) (citing *Astiana v. Hain Celestial Grp., Inc.*, 783 F. 3d  
7 753, 761 (9th Cir. 2015)). Similarly, the primary jurisdiction doctrine does not apply just because  
8 the FDA is investigating facts also at issue in concurrent consumer litigation. *See In re 5-Hour*  
9 *Energy Mktg. & Sales Practices Litig.*, No. MDL 13-2438 PSG (PLAx) 2014 U.S. Dist. LEXIS  
10 149732 (C.D. Cal. Sep. 14, 2014). In *5-Hour Energy*, the defendant moved to stay false labeling  
11 claims in deference to an investigation being conducted by the FDA. The court rejected the  
12 argument because resolution of the state law claims did not depend on either an “FDA ruling” or the  
13 FDA’s “particular expertise.” *Id.* at \*37 (citing *Chavez v. Blue Sky National Beverage Co.*, 268  
14 F.R.D. 365, 375 (N.D. Cal. 2010)). Indeed, “[t]he mere existence of an agency investigation does  
15 not weigh in favor of a referral under the primary jurisdiction doctrine.” *Id.* at \*38-39.

16 In practice, courts routinely decline to apply the primary jurisdiction doctrine in cases  
17 concerning product recalls. *See, e.g., Philips v. Ford Motor Co.*, No. 14-cv-02989-LHK, 2016 U.S.  
18 Dist. LEXIS 22020, at \*\*35-36 (N.D. Cal. Feb. 22, 2016) (declining to apply doctrine where “recall  
19 does not provide California Plaintiffs with all of the relief that they seek”); *In re Toyota Motor*  
20 *Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig.*, 754 F. Supp. 2d 1145,  
21 1199 (C.D. Cal. 2010) (rejecting doctrine where the defendant “has not shown that an actual conflict  
22 exists” between preliminary injunction and government investigation); *Kent v. DaimlerChrysler*  
23 *Corp.*, 200 F. Supp. 2d 1208, 1218-19 (N.D. Cal. 2002) (finding no conflict between ongoing recall  
24 and relief sought). Courts in this district have also generally declined to apply the primary  
25 jurisdiction doctrine in cases involving the FDA “absent concrete evidence that the FDA is currently  
26 involved in creating a new regulation concerning the subject of the lawsuit.” *Trazo v. Nestlé USA,*  
27 *Inc.*, No. 5:12-cv- 2272-PSG, 2013 U.S. Dist. LEXIS 113534, at \*21 n.55 (N.D. Cal. Aug. 9, 2013).  
28 Defendant makes no such contention here.



Defendant confusingly argues that unless the primary jurisdiction doctrine is invoked, “KDP could be subject to different recall orders from different federal authorities—one from this Court and one from the FDA.” Def’s Br. at p. 24. But Keurig has already announced that it has withdrawn Peñafiel from the market due to “arsenic at levels that exceeded the FDA’s bottled water standards for mineral water of 10 ppb” Cplt. ¶ 25; Sipos Decl., Ex. C. Thus, it is unclear how a product it already withdrew from the market could somehow be subject to “different recall orders.”

Keurig also argues that this is a case of first impression necessitating agency expertise of the regulations applicable to carbonated bottled water. However, as explained earlier, Keurig misreads the federal regulations. *See supra*, Section I.A. In any event, Keurig expressly admitted that Peñafiel contained arsenic levels that were “violative” of the FDA regulations. Cplt. ¶ 25; Sipos Decl., Ex. C. Thus, to the extent there is any ambiguity in the FDA’s bottled-water regulations, Keurig’s admission that it violated the law dispenses with Keurig’s request for further FDA guidance.

This case does not require the Court to interpret complex regulations, resolve technical issues, or engage in policy judgments that require the expertise of the FDA. It does not involve particularly complicated issues, and this Court is “well-equipped to handle” claims asserting “that defendant has violated FDA regulations and marketed a product that could mislead a reasonable consumer.” *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1124 (N.D. Cal. 2010); *see also Jones v. ConAgra Foods, Inc.*, 912 F. Supp. 2d 889, 898-99 (N.D. Cal. 2012) (“[A]llegations of deceptive labeling do not require the expertise of the FDA to be resolved in the courts, as every day courts decide whether conduct is misleading.”). The relief requested will not interfere with the FDA’s jurisdiction, nor is it dependent on the outcome of any FDA testing. Keurig has already admitted its wrongdoing.

Plaintiff is entitled to prosecute his state-law claims and need not wait for additional federal regulatory proceedings, which may or may not occur. Accordingly, the doctrine of primary jurisdiction does not apply, and the case should not be stayed or dismissed.

### **CONCLUSION**

For the reasons stated above, Defendant’s motion to dismiss the Complaint should be denied. If it is granted in any respect, Plaintiff requests and should be granted leave to amend.

1 DATED: September 9, 2019

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